IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., *Plaintiff*, v. TEVA PHARMACEUTICALS USA, INC., et al., *Defendants*.	§ § § § § § § § § §	Case No. 2:15-cv-1455-WCB

MEMORANDUM OPINION AND ORDER

Before the Court is plaintiff Allergan, Inc.'s Motion to Compel Discovery, Dkt. No. 205, which seeks to compel responses to Interrogatories Nos. 3 and 5 from defendant Mylan Pharmaceuticals, Inc., and Mylan, Inc., ("Mylan"). The motion has been fully briefed and was argued during a telephonic hearing conducted on January 11, 2017. The Court GRANTS the motion.

BACKGROUND

Along with several other defendant pharmaceutical companies, Mylan is seeking approval by the Food and Drug Administration ("FDA") to sell a generic version of Restasis, an ophthalmic product sold by Allergan that is indicated for the treatment of keratoconjunctivitis sicca and dry eye disease. To obtain FDA approval of a generic drug through the filing of an Abbreviated New Drug Application ("ANDA"), it is necessary for the generic manufacturer to show that the generic drug is bioequivalent to the previously approved drug. The FDA has issued several guidance documents setting forth what is required to show bioequivalence for generic versions of Restasis. See, e.g., Dkt. No. 205-1 (Draft Guidance on Cyclosporine (Oct.

2016)). Mylan's ANDA No. 205894 therefore aims to establish that its generic product is bioequivalent to Restasis.

When Mylan filed its ANDA with the FDA, it submitted a "paragraph IV certification" that the related patents held by Allergan are "invalid or will not be infringed by the manufacture, use, or sale" of its generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). In response, Allergan filed a complaint pursuant to the Hatch-Waxman Act, Pub. L. No. 98-417 (1984), alleging infringement of U.S. Patent Nos. 8,629,111; 8,633,162; 8,642,556; 8,648,048; 8,685,930; 9,248,191. Allergan's infringement contentions rely on, inter alia, Mylan's representations of bioequivalence, which Mylan submitted to the FDA. See, e.g., Dkt. No. 205-3, at 18, 31. Allergan contends that evidence of bioequivalence supports Allergan's claims of infringement for at least the patent claims that are directed to clinical efficacy. See, e.g., Dkt. No. 96-1 (Claims 11 and 17 of U.S. Patent No. 8,629,111, col. 15, ll. 45-48, and col. 16, ll. 16-18).

Allergan's first set of interrogatories to Mylan, served in March of 2016, included requests regarding Mylan's ANDA and its bioequivalence evidence. Dkt. No. 205, at 2-3. Interrogatory No. 3 states:

> Identify the persons at Mylan most knowledgeable regarding: (a) medicaments for treating dry eye disease; (b) use of a cyclosporine-A emulsion to treat dry eye disease; (c) topical medicaments for treating dry eye disease; (d) ANDA No. 205894; (e) your Paragraph IV Notifications; and (f) Restasis®.

Interrogatory No. 5 states:

> Describe fully and with particularity the basis for the assertion in ANDA No. 205894 that Your Proposed Product is bioequivalent to Restasis®, and identify the persons most knowledgeable about the information requested in this interrogatory.

Mylan initially refused to answer the two interrogatories, setting forth only boilerplate objections and a statement that bioequivalence is irrelevant to infringement. In December of

2016, however, Mylan supplemented its responses. Dkt. No. 205-5. Mylan identified two individuals in response to Interrogatory No. 3(d). Id. at 3. For Interrogatory No. 5, Mylan pointed Allergan to the production of Mylan's ANDA and its FDA correspondence, "which contain documents from which information responsive to this interrogatory may be derived." Id. at 3-4.

Allergan has moved to compel Mylan to identify individuals for the remaining topics listed in Interrogatory No. 3. Allergan has also asked for any bioequivalence documentation that Mylan submitted to the FDA to comply with the FDA's most recent draft guidance, which was issued in October 2016, Dkt. No. 205-1. Finally, Allergan wants Mylan to provide documentation relating to its bioequivalence assertions, beyond what is contained in Mylan's submissions to and correspondence with the FDA.

DISCUSSION

The Court has broad discretion to decide motions to compel discovery of documents. Imperial Ethiopian Gov't v. Baruch-Foster Corp., 535 F.2d 334, 337 n.8 (5th Cir. 1976). The scope of discovery is limited by Fed. R. Civ. P. 26(b)(1), which allows for

> discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

The parties first argue about whether bioequivalence information in general is relevant to Allergan's infringement case. It clearly is. Courts have found that bioequivalence is relevant in infringement cases. See, e.g., Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1289 (Fed. Cir. 2010) (noting that fact-finder could determine that patent was infringed

based on, in addition to other evidence, bioequivalence data). For example, courts have found that bioequivalence is relevant to the function prong of the function-way-result test for the doctrine of equivalents. See Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1298 (Fed. Cir. 2009) (en banc); see also, e.g., Intendis GMBH v. Glenmark Pharms. Inc., 822 F.3d 1355, 1361-62 (Fed. Cir. 2016) (affirming judgment that Glenmark's accused drug product infringed under the doctrine of equivalents based on, inter alia, Glenmark's ANDA, which was "[f]atal to Glenmark's argument" because it "included repeated statements that [its] excipient and the claimed excipients function as penetration enhancers").

Bioequivalence can also be directly relevant to claims that contain limitations directed to biological functionality. Given that Mylan is seeking to obtain FDA approval by showing that its generic product functions similarly to Restasis, Mylan's evidence that supports the bioequivalence of its product with Restasis also supports Allergan's claim of infringement of Allergan's patent claims that contain functional limitations. See, e.g., U.S. Patent No. 8,629,111, col. 15, ll. 45-48 (Claim 11: "The topical ophthalmic emulsion of claim 1, wherein, when the topical ophthalmic emulsion is administered to an eye of a human, the blood of the human has substantially no detectable concentration of cyclosporine A.").[1]

Mylan is correct that establishing bioequivalence for purposes of FDA approval is not the same as establishing equivalence for purposes of proving patent infringement. Abbott, 566 F.3d at 1298 (noting that, "while potentially relevant, the bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by

[1] Evidence of bioequivalence to support infringement under doctrine of equivalents is relevant to more than those claim elements that explicitly describe a function. See Intendis, 822 F.3d at 1362 (function of the claimed element need not be described in the intrinsic evidence, as long as the function of the claimed element is understood by one of skill in the art).

equivalents."). But Mylan is wrong to say bioequivalence is not relevant when the asserted claims relate to function, and it cites no support for that proposition.[2]

Nor is there any force to Mylan's argument that its ANDA submissions have no significance because it is the FDA that makes the final determination of bioequivalence. There is "no reason why a district court acting as a fact finder should ignore a party's representation to a federal regulatory body that is directly on point." Intendis GMBH v. Glenmark Pharms. Inc., 822 F.3d at 1362.

Interrogatory No. 3

Mylan has answered interrogatory number 3 in part, but it has refused to provide the names of individuals as requested in subparts (a)-(c) and (e)-(f) of the interrogatory on the ground that the requests are overbroad or that Allergan already has the information. The grounds of objection are not persuasive.

First, the requests that ask for Mylan to identify persons knowledgeable about topical and other medicaments for treating dry eye disease, as well as about the use of cyclosporine-A to treat dry eye disease, (subparts (a)-(c)) are not overbroad but fall within the broad definition of relevant information in Fed. R. Civ. P. 26(b)(1). Those requests are not solely directed to expert testimony, as Mylan argues. Mylan's contention that it intends to offer only expert testimony on these points does not respond to Allergan's need for that information in order to conduct fact

[2] The decision in Eli Lilly & Co. v. Wockhardt Ltd., No. 1:08-cv-1547, 2010 WL 2195436, at *2 (S.D. Ind. May 27, 2010), is distinguishable on exactly that ground. In that case the court denied a motion to compel the production of bioequivalence studies because "Lilly does not dispute Wockhardt's contention that "[n]one of the asserted claims . . . require Wockhardt's ANDA products to have any particular biological performance of any kind." Here, as noted, various of the asserted claims require just such "particular biological performance."

discovery regarding Mylan's development of its generic and related products. See Dkt. No. 242, at 5.

Second, Mylan has offered no satisfactory explanation for its refusal to provide the names of persons knowledgeable about its Paragraph IV certifications and Restasis (subparts (e)-(f)). Allergan is not asking for production of documents; rather, it is asking for a list of knowledgeable individuals. Therefore, Mylan's reference to its offer to provide corporate testimony related to Restasis is insufficient. And Mylan's objection on the ground of privilege to identifying attorneys as the individuals knowledgeable about the Paragraph IV certifications is baseless: Supplying attorney names does not reveal client confidences. Moreover, Allergan's request is not, as Mylan suggests, "simply a matter of identifying the attorneys who signed the letters" of the notices regarding Paragraph IV certifications." Dkt. No. 242, at 5. It is possible, even likely, that more persons worked on the certifications than the few who signed the letters. And, in any event, Mylan is in the better position to compile that list, as it has direct knowledge of the individuals who worked on those certifications. See Fed. R. Civ. P. 26(b)(1) (noting "the parties' relative access to relevant information" as a consideration in discovery).

Interrogatory No. 5

Even though bioequivalence information is relevant, Mylan contends that Allergan already has the information it seeks relating to Interrogatory No. 5. Mylan's argument is that its ANDA and FDA correspondence, including all representations regarding bioequivalence, has been produced and contains all the information that Allergan needs with respect to that interrogatory. Mylan also states that it has produced and will continue to produce, in accordance with the local rules, all correspondence responding to the FDA's most recent October 2016 guidance. Dkt. No. 228, at 4-5 & n.1; Dkt. No. 242, at 1. Furthermore, Mylan has agreed to

provide corporate testimony on its compliance activities regarding the FDA's guidance. Dkt. No. 228, at 5; Dkt. No. 242, at 2.

Allergan stated during the hearing that the material it is interested in is documentation reflecting internal deliberations and testing directed to the issue of bioequivalence of Mylan's product and Restasis. Moreover, Allergan stated that it appears that Mylan's deadline for complying with the FDA's most recent draft guidance on bioequivalence may fall after the trial in this case. Mylan did not deny that assertion. Mylan's current and ongoing correspondence with the FDA, therefore, may not include Mylan's documentation supporting bioequivalence that has been generated and continues to be generated, but has not yet been submitted to the FDA and may not be submitted until after trial. That information, to the extent any exists, is relevant. Mylan is therefore directed to produce any documentation of internal deliberations and testing regarding compliance with the FDA's October 2016 guidance as to bioequivalence.

Finally, for the same reasons discussed above regarding Interrogatory No. 3, Mylan is directed to identify the persons most knowledgeable about the bioequivalence assertion in its ANDA.

IT IS SO ORDERED.

SIGNED this 12th day of January, 2017.

William C. Bryson

WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE